DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

1401 Rockville Pike
Rockville MD 20852-1448

Our Reference Number: 99-0909

Roberta L. McKee, Ph.D.
Merck & Co., Inc.
P.O. Box 4
Sumneytown Pike
West Point, PA 19486

AUG 27 1999

Dear Dr. McKee:

The Supplement to your License Application for Hepatitis B (Recombinant) Vaccine, to include the use of a preservative-free — µg/mL bulk alum product for the introduction of preservative-free pediatric/adolescent final containers (5 µg/0.5 mL vials), has been approved. This information will be included in your License Application file.

Expiration dating will be 36 months for the 5 µg/0.5 mL thimerosal free final container vial presentation.

We acknowledge the commitment outlined in your letter of August 26, 1999, to incorporate sterility testing at each specified time interval of 0,3,6,9,12, 24, and 36 months as stated in your stability testing schedule and to report the real time stability data to CBER as they become available rather than in your Product Annual Report.

We also acknowledge your withdrawal of the _____ _____ of the current submission and understand that you will submit another supplement at a later time when stability data and appropriate demonstration of _____ are available.

Please submit three copies of final printed labeling, under label review number 19990811002, at the time of use and include part II of the label transmittal form with completed implementation information.

Sincerely yours,

P. Patriarca

Peter A. Patriarca, M.D.
Director
Division of Viral Products
Office of Vaccines
Research and Review
Center for Biologics
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